K072242

510(k) Summary of Safety and Effectiveness (in accordance to 21 CFR 807.87(h))

Device Name
Proprietary Device Name:COR Analyzer II

Establishment Name and Registration Number of Submitter

Name: RCADIA Ltd. (RCADIA hereafter)
Registration: In process
Submission contact: Dan Laor
Sireni 6, Haifa 32972, Israel
TEL: 972-4-8246632

SEP 11 2007

Device Classification

Product Code:	LLZ
Subsequent Product Code:	JAK
Regulation Number:	892.2050
Common Name:	PACS - Picture archiving &communications system
Classification Name:	Picture archiving and communications system
Regulatory class:	Class II

Reason for 510(k) Submission
Special 510(k) Submission

Identification of Legally Marketed Equivalent Devices
K061624 *Vitrea2*, K063548 COR Analyzer I

Device Description
COR Analyzer I is a post processing software application which runs on a stand-alone Windows based work-station. The device input is Computed Tomography Angiography (CTA) set of images. The received data is displayed on the workstation screen, reviewed and selected by the operator for processing. Software provides the location and segmentation of the coronary artery tree. The software also labels the coronary arteries and displays them uniquely colored in a 3D view. The artery changes of volumes are processed and deviations from expected values are detected. When a deviation exceeds threshold value it is displayed on the 3D view.

Indications for use
The COR Analyzer II is intended to assist a trained physician to analyze Computed Tomography (CT) Angiographic images. The device is not intended for use with mammography. The COR Analyzer II is specifically indicated to provide visualization of the major coronary vessels and lesions, thus assisting the physician in visualizing the coronary anatomy and pathology. COR Analyzer II has abilities for coronary vessels segmentations, abnormalities display and processing.

Safety & Effectiveness
The device has been designed, verified and validated complying with 21CFR 820.30 regulations. Bench and clinical data demonstrate that the COR Analyzer II meets the required specifications. No adverse affects have been detected.

Substantial Equivalency
It is Rcadia Medical Imaging Ltd. opinion that the COR Analyzer II is substantially equivalent in terms of indications for use, safety and effectiveness to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

RCADIA Medical Imaging, Ltd.
% Mr. Dan Laor
Managing Director
Quasar Quality Ltd.
6 Sireni
Haifa
Israel 32972

SEP 11 2007

Re: K072242
Trade/Device Name: COR Analyzer II
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: August 12, 2007
Received: August 13, 2007

Dear Mr. Laor:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: COR Analyzer II

Indications For Use:

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Prescription Use **X** AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K072242